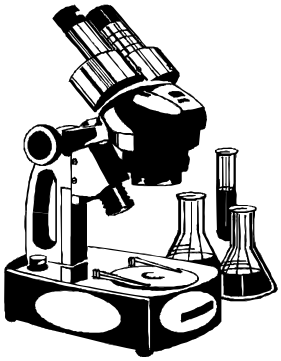
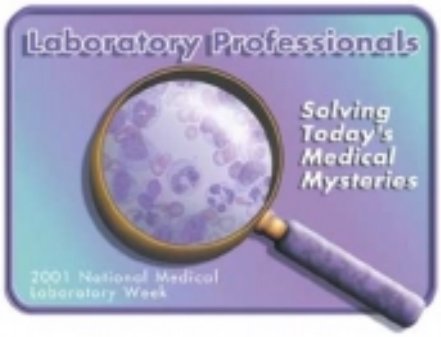


CLIA BITS

North Dakota Department of Health
Division of Health Facilities

Spring 2001

National Medical Laboratory Week



Laboratory professionals are gearing up to celebrate the 2001 National Medical Laboratory Week April 15 through 21. The theme for this year's Lab Week is Solving Today's Medical Mysteries. Laboratory professionals are an integral part of the health care team. Take some time during National Medical Laboratory Week to celebrate the difference you make in the delivery of health care. Happy Lab Week!

CLIA Extension

On Dec. 29, 2000, the final rule with comment period entitled, "Medicare, Medicaid and CLIA Programs; Extension of Certain Effective Dates for Clinical Laboratory Requirements under CLIA," HCFA-2024-FC2, was published in the Federal Register. This final rule extends the phase-in date of the quality control requirements applicable to moderate and high complexity tests. It also extends the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing. Both dates were extended to Dec. 31, 2002. The dates were extended to allow additional time to develop regulations that address new technology issues and to review the qualifications required for a laboratory director.

The Stark Rule

On Jan. 4, 2001, the Health Care Financing Administration (HCFA) issued phase one of its final rule with comment period, "Physician's Referral to Health Care Entities With Which They Have Financial Relationships," also known as the "Stark" rule in reference to Representative Fortney "Pete" Stark from California. Representative Stark introduced the original legislation that prohibited a physician from referring a patient to a provider for clinical laboratory services if the physician or the physician's immediate family member had a financial relationship with the service provider. Further modifications to the law also barred other health service providers from making self-referrals. Exeptions to this ban on self-referrals are addressed in regulation. More information can be found at www.aphl.org.

Expanded Study Shows Problems

Preliminary results from a Health Care Financing Administration (HCFA) study on waived laboratories finds that many labs are testing beyond their certificate complexity level and that some are not following manufacturer's instructions, as required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The preliminary findings were discussed at the Feb. 7 and 8, 2001, meeting of the Clinical Laboratory Improvement Advisory Committee. In 2000, two independent surveys of waived and provider-performed microscopy (PPM) laboratories in Ohio and Colorado found that 50 percent of the 100 laboratories visited demonstrated quality problems and 10 percent tested outside their certificate level. Based on these results, HCFA expanded a pilot study to eight states to examine a 5 percent sample of certificate of waiver and PPM laboratories. The survey of labs in those states recently was completed and showed laboratories are testing beyond their certificate complexity level and either do not have or are not following manufacturer's instructions. A final report indicating specific survey data is expected later this spring.

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There is little difference in people, but that little difference makes a big difference. That little difference is attitude. The big difference is whether it is positive or negative.

--W. Clement Stone

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Normal Reference Ranges

Clinical laboratory tests are reported to the requesting physician with "reference ranges" that aid in the interpretation of the patient's specific result for each test. Many reference ranges are age and/or sex specific. The reference range for a given test, in most cases, gives the physician the values that encompass the central 95 percent of "normal" patients in that age/sex group. That means 5 percent of "normal" individuals may have values slightly below or slightly above the reference range presented. (Usually 2.5 percent of normal patients will have values below the lower limit of the reference range; 2.5 percent above the upper limit if the reference range is an ideal.) Notable exceptions to this rule are some values (e.g. total, high-density lipoprotein [HDL] and low-density lipoprotein [LDL] cholesterols) where "target" values, in this case recommended by the National Cholesterol Education Program, are presented as being desirable for optimal health. In this type of situation, more than 5 percent of the "normal" population may fall outside the reference range presented with a specific test result.

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